

Small Plant Assistance Module

Small Business Regulatory Enforcement Fairness Act (SBREFA)

OBJECTIVE

After completing this module, you will be able to:

1. Identify FSIS activities related to SBREFA.

RESOURCE MATERIALS

Directive 5XXX DRAFT- **The Small Business Regulatory Enforcement Fairness Act (SBREFA)**

INTRODUCTION

The Small Business Regulatory Enforcement Fairness Act (SBREFA) is a regulatory reform statute that was passed by the 104th Congress and signed into law by President Clinton March 29, 1996. SBREFA (Public Law 104-121) contains a variety of provisions, some affecting Federal Agency regulations. For example, SBREFA provides for Congressional review of Federal regulations, including those promulgated by FSIS, before the regulations can take effect.

SBREFA also provides a number of protections for small businesses against what they may regard as unfair actions by Federal regulatory agencies. Thus, SBREFA gives small businesses expanded authority to go to court and seek awards for attorneys' fees and costs when an Agency has been found excessive in its enforcement of regulations. Also, each Federal Agency is required to establish a policy to provide for the reduction, and in some circumstances, the waiver of civil penalties for violations of a regulation. There are two major areas you should be aware of: enforcement fairness, and advocacy.

KEY PROVISIONS

Let's review some of the key provisions and discuss how they may relate to your role as a Public Health Veterinarian. First, according to SBREFA, agencies must assist small businesses in understanding and complying with the regulations. FSIS has a staff at headquarters charged with providing small and very small plants with access to such assistance. You may be involved in helping the small and very small establishment owners and operators gain access to information that the agency supplies to assist them. Second, SBREFA requires the Small Business Administration (SBA) Administrator to appoint a small business and agriculture regulatory-enforcement ombudsman and 10 regional small business regulatory fairness boards to comment on the enforcement activities of federal regulatory agencies. SBA has appointed such a National Ombudsman and 50 small business owners to serve on the regional Regulatory Fairness Boards. The Office of the National Ombudsman and the Fairness Boards have instituted procedures for small businesses or other small entities -- such as small towns or non-profit organizations -- to present information concerning the compliance or enforcement experiences with Federal regulatory agencies that they or the people they represent have had. The National Ombudsman and the Fairness Boards can receive information from small businesses or other small entities concerning their interactions with Federal agencies, hold follow-up meetings on the concerns of these entities, report on significant enforcement issues, and reflect all concerns in their reports to Congress. They cannot, however, adjudicate the complaints they receive or reverse Agency decisions. The National Ombudsman must annually report to Congress on findings on complaints and progress of the Regulatory Fairness program. From time to time, FSIS is asked to report on or respond to matters brought before the National Ombudsman or one of the Fairness Boards. Along with other USDA and Government agencies, FSIS has been asked to contribute information on its regulatory fairness policies that is ultimately reflected in the National Ombudsman's report to Congress.

FSIS personnel involved in inspection and enforcement activities should be aware that the National Ombudsman and the Fairness Boards provide, in a sense, an alternative avenue of appeal for the small businesses we regulate. In other words, in addition to

appealing Agency actions through the FSIS chain of command and in addition to making their concerns known by other means, the owners or managers of small official establishments may also make their concerns known to the National Ombudsman or their regional fairness board.

What qualifies an establishment to be a small business? The definitions FSIS used for the phased in implementation of HACCP were modeled after SBA's definitions. According to the definition, a small plants is one having 10 or more but fewer than 500 employees. A very small establishment is defined as having fewer than 10 employees or annual sales of less than \$2.5 million. FSIS allows establishments to "self identify," meaning that we require no proof that they fall into one category or another.

An Ombudsman is a person who has a proxy to represent someone. In government, a person who represents persons who complain about alleged wrongdoings of the public administration. In the SBA, National Ombudsman represents small businesses in their dealings with Federal regulatory agencies.

There are 10 Regional Fairness boards throughout the U.S. Members of this board are small business owners elected by other small business owners. Board meetings are scheduled and posted to website. Issues must be scheduled for presentation at meetings/hearings. The meetings are open to public. The boards offer an additional avenue of appeal for small business entities. However, the board does not replace our FSIS appeal processes. The Board cannot overturn or adjudicate Agency decisions.

The SBA reports to Congress and "grades" agencies on how well they are doing to meet the goals of SBREFA.

Here are the web sites that will give you more information on SBREFA.

<http://app1.sba.gov/calendar/ombudsman/calendar.cfm-meeting> dates calendar

<http://www.sba.gov/ombudsman/dspboards.html-regions> and information

The SBA website shows the dates of board meetings. FSIS receives notification if there is an agency-related issue that will be presented. The District Office deals with attendance at these meetings and presenting information as required.

Here are the Agency contacts for SBREFA Board meetings.

Barbara Masters, OFO	(202) 720-8803
Cheryl Hicks, OFO	(202) 690-2709
Daniel Engeljohn, OPPD	(202) 205-0495
Chuck Williams, OPPD	(202) 720-3885
Ron Hicks, PEER	(202) 720-8609
Scott Safian, PEER	(202) 418-8872
Mary Cutshall, Strategic Initiatives/Outreach	(202) 690-6520

Comments from small business entities flow through the SBA Contact to FSIS. FSIS reports to the SBA on SBREFA activities through OBPA (Office of Budget and Program Analysis).

So far, here are the common issues that have been brought before the review board:

- Scientific support for hazard analysis
- Validation - reliance on literature without validation in the plant's environment

The staff in FSIS currently responsible for providing access to information to small and very small plants is the Strategic Initiatives, Partnerships, and Outreach Staff. Here are some services they offer:

- Guidance and Assistance Material
- Contact/Coordinator Network
- Participation in meetings
- Development of Material
- Provide off-set costs for Universities

The staff was established for these reasons:

- FSIS recognized unique needs of small and very small plants with HACCP implementation
- Administrator created the Office of National HACCP Small and Very Small Plant Coordinator in 1998
- Perspective - all but 300 of the plants regulated are small.

Current accomplishments of the staff include:

- Demonstration projects begun
- Contact Coordinator network formed
- Generic Models Developed
- Small Plant Meetings
- Generic Models Revised
- Self-Study Guide
- Continuous correlation

Ongoing activities include:

- New materials developed on an ongoing basis
- Existing material distributed
- Contact/coordinator network maintained
- Interaction with Extension Universities
- FSIS website to be revamped - better access to materials for small business interests

The EIAO's are responsible for distributing information to owners/operators of small and very small plants. Here are some things the EIAO will do:

- Provide access to materials/resources
- Provide technical assistance using the HACCP workbook as a guide
- Refer small business owners to coordinators
- Conduct a food safety assessment
- Provide information to assist with implementation of a new or unique process
- Provide information to assist with new employees and turnover
- Provide information for ongoing or new enforcement action
- Assist in increasing the level of understanding of HACCP

EIAO's also do the following:

- Attend meetings and present information on Small Plant Outreach.
- Share information on the Strategic Initiatives, Partnerships, and Outreach office in Washington.

FSIS will continue to develop guidance and assistance materials and make these available to EIAO's and small plants.

As a PHV, at some point, the Agency has plans to train you to perform EIAO duties. Until you are trained, simply refer any requests for information from small and very small plants to the EIAO trained individuals in your District.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

DRAFT
5XXX
series

XX/XX/02

The Small Business Regulatory Enforcement Fairness Act (SBREFA)

I. PURPOSE

This Directive sets out the roles and responsibilities of Agency programs and personnel with respect to the Small Business Regulatory Enforcement Fairness Act (SBREFA) and, in particular, the National Ombudsman program.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

APA
RFA
SBA
SBREFA

V. ABBREVIATIONS AND FORMS

ABA	Administrative Procedure Act
OBPA	Office of Budget and Program Analysis, USDA
OFA	Office of Field Operations, FSIS
OM	Office of Management, FSIS
OMB	Office of Management and Budget
ONO	Office of National Ombudsman
OPPD	Office of Policy and Program Development, FSIS
RFA	Regulatory Flexibility Act
SBA	Small Business Act
SBREFA	Small Business Regulatory Fairness Act

UMRA Unfunded Mandates Reform Act

VI. **BACKGROUND**

A. Small Business Regulatory Enforcement Fairness Act – What it is and what it does

The Small Business Regulatory Enforcement Fairness Act (SBREFA – pronounced “sub-reef-uh”) is a regulatory reform statute that was passed by the 104th Congress and signed into law March 29, 1996.

Key provisions:

1. Compliance Guidance

SBA and agencies issuing regulations must assist small business in understanding and complying with the regulations.

2. National Ombudsman and Fairness Boards

The Small Business Administration (SBA) Administrator must appoint a small business and agriculture regulatory-enforcement ombudsman and 10 regional small business regulatory fairness boards to comment on the enforcement activities of federal regulatory agencies. SBA has appointed such a **National Ombudsman** and 50 small business owners to serve on the regional **Small Business Regulatory Fairness Boards**. The Office of the National Ombudsman and the Fairness Boards have instituted procedures for small businesses or other small entities -- such as small towns or non-profit organizations -- to present information concerning the compliance or enforcement experiences that the small entities have had with Federal regulatory agencies.

The National Ombudsman and the Fairness Boards can receive information from small businesses or other small entities concerning their interactions with Federal agencies, hold follow-up meetings on the concerns of these entities, report on significant enforcement issues, and reflect all concerns in their reports to Congress. They cannot, however, adjudicate the complaints they receive or reverse Agency decisions. The National Ombudsman must annually report to Congress on findings on complaints and progress of the Regulatory Fairness program.

SBREFA allows for the reduction or waiver in certain circumstances of civil penalties for violations of statutory or regulatory requirements.

a. What’s an Ombudsman?

An ombudsman is a person who has a proxy to represent somebody. In government, an ombudsman is a person who represents people or persons who complain about alleged wrongdoings of the public administration.

The word “ombudsman” is Swedish and literally means “representative.” In its constitutional reform of 1809, Sweden established a high legal officer, elected by the Parliament, called the “High Ombudsman,” to supervise the legality of the activities of the government and public administration.

Today, many governments and large companies around the world have established ombudsmen to represent their constituents and customers who have encountered problems in their dealings with those large, complex organizations. Thus, the National Ombudsman at the Small Business Administration represents small businesses in their dealings with Federal regulatory agencies.

3. Equal Access to Justice Act Amendment

Under some circumstances, companies or persons can be awarded attorney’s fees or court costs if an agency has imposed unreasonable or excessive fines after a judgment. Also, each Federal agency is required to establish a policy to provide for the reduction, and in some circumstances, the waiver, of civil penalties (such as fines) for violations of statutory or regulatory requirements. This provision of SBREFA has only a limited effect on FSIS the Agency has only limited authority to impose civil penalties.

4. Regulatory Flexibility Act amendments

In the case of a proposed rule for which a regulatory flexibility analysis is required (a rule that will have a significant economic impact on a substantial number of small entities):

- a. The regulatory flexibility analysis is subject to judicial review. Federal courts may order corrective action on such analysis and defer enforcement of a rule if they find the analysis defective.
- b. The Agency must send a copy of its proposed rule and a copy of the initial regulatory flexibility analysis, or determination that such analysis is not required, to the SBA for comment.

5. Congressional Review Act provisions

An agency must submit its rules to Congress and the General Accounting Office (GAO) before they can take effect. (GAO is to

prepare a report on each major rule to assure the Agency has complied with procedural requirements regarding cost-benefit analysis, regulatory flexibility analysis, and specified sections of the Unfunded Mandates Reform Act (P.L. 104-4).

B. FSIS Responsibilities under SBREFA

1. FSIS Activity under the Congressional Review Act

FSIS sends copies of final rules and other information to the Comptroller General of the United States and to the Senate and the House of Representatives just as soon as the rules are published. Under SBREFA, Congress may disapprove a final rule. Congress has 60 days in which it may disapprove a final rule that is deemed "major." A major rule is one that will have an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, industries, or governments; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based industries to compete with foreign businesses.

2. FSIS Obligations under SBREFA Civil Penalty Assessment Provisions

FSIS currently has authority to impose civil penalties only for violations of the shell-egg storage and handling regulations. FSIS Directive 8840.1 explains the Agency's policy for enforcing these regulations. After finding violations of the temperature or labeling requirements in these regulations, FSIS may issue letters of information or warning or "present your views" letters, or take other appropriate action. In addition, FSIS may seek appropriate criminal or civil penalties. In assessing civil penalties, the Agency takes into account the gravity of the violation, degree of culpability, and history of prior offenses.

3. FSIS and the Office of the National Ombudsman

From time to time, FSIS is asked to report on or respond to matters brought before the National Ombudsman or one of the Fairness Boards. Along with other USDA and Government agencies, FSIS has been asked to contribute information on its regulatory fairness policies that is ultimately reflected in the National Ombudsman's report to Congress.

C. Further Information on SBREFA and the National Ombudsman

Further information on SBREFA and the activities of the National Ombudsman and the regional fairness boards can be found on the RegFair web site "<http://www.sba.gov/ombudsman>." The information posted on the RegFair web site directly addresses small businesses and other small entities and provides a

"Federal Agency Appraisal Form" that they can use to relate their experiences with the Federal agencies they deal with.

VII. OFFICE OF FIELD OPERATIONS

A. Role of Field Operations Personnel

FSIS personnel involved in inspection and enforcement activities should be aware that the National Ombudsman and the Fairness Boards provide an alternative avenue of appeal for the small businesses we regulate. In other words, in addition to appealing Agency actions through the FSIS chain of command and making their concerns known by other means, the owners or managers of small official establishments may also make their concerns known to the National Ombudsman or their regional fairness board. This is just another reason why we must always try to do our best to make sure that our decisions are sound, fair, and impartial.

[Consider moving this paragraph.] Currently, only a handful of cases involving FSIS-regulated businesses are annually brought to the attention of the National Ombudsman or the SBREFA fairness boards. When the National Ombudsman or the SBREFA fairness board brings a matter involving meat, poultry, or egg product regulation to the Agency's attention, the Agency is expected to solve the problem and report back to the Office of the National Ombudsman in a timely manner. OPPD coordinates the Agency's response, relying on information provided by the Office of Field Operations and other Agency staffs.

B. Role of Consumer Safety Officer in SBREFA matters

1. Consumer Safety Officers (CSO's) play a dual role in the Agency's SBREFA efforts. First, they provide technical guidance to assist small and very small establishments, especially in helping them understand how to comply with the SSOP and HACCP regulations. They deal directly with small and very small plants, providing them guidance and assistance when the plants have problems complying with the regulations.

a. What do we mean by "small and very small plants?"

FSIS sometimes implements new regulations first in the largest and later in the smaller establishments in order to make the transition to the new regulations easier for small businesses. Currently the Agency uses the following criteria for establishment size:

Large – more than 500 employees
Small – 500 or fewer employees

Very small – fewer than 10 employees or annual sales of less than \$2.5 million

2. CSO's are advocates for small plants within FSIS. They attend meetings with Agency staffs and present information on the Agency's small plant outreach activities. FSIS headquarters staffs develop guidance materials and make them available to the CSO's.
3. An important duty of the CSO's is to represent FSIS at meetings of the SBA's Regional Fairness Boards.

C. CSO attendance at Small Business Regulatory Fairness Board Meetings

The CSO should:

1. Consult the National Ombudsman's calendar (at <http://app1.sba.gov/calendar/ombudsman/calendar.cfm>) and know when SBREFA-related events will be taking place.
2. Plan to attend Fairness Board meetings in the CSO's district. Especially plan to attend if the Washington Office has notified the District Office or the CSO that FSIS-regulated businesses are to present testimony at the meeting.
3. Keep the District Manager informed of any Ombudsman events that are to take place in the District.
4. Be prepared to speak on behalf of the Agency at the Fairness Board meetings and present information on the small and very small plant outreach program, including current program activities. Issues involving FSIS may be raised by Board members or persons testifying or commenting at the meetings. (For their talks, the CSO's can use documents or presentation templates they receive in their training.) If the Agency's Washington Office has been able to identify an issue that is to be presented at the meeting, an attempt will be made to contact the CSO and the district office before the meeting and to provide the CSO with information on the matter.
5. Know the Agency contacts in the District, at the Technical Service Center, or at Headquarters to be consulted in addressing an issue or in working toward the solution of a problem. Know also the Agency SBREFA contacts.
6. Deal with the issue presented but do not feel compelled to resolve a difficult problem on the spot. A complicated issue or one with national

implications will have to be addressed by Agency staffs in the field or at Headquarters.

7. Be prepared to report to the District Office and to the Washington Office on issues involving FSIS or other USDA agencies. Regional Fairness Board meetings address relations between small businesses and Federal regulatory agencies, including USDA agencies. The CSO may be the only USDA representative at a Fairness Board meeting. If that is the case, and an issue involving a USDA agency other than FSIS is presented, the CSO should make an effort to learn what the issue is and report it to the Washington Office. Headquarters personnel will bring the matter to the attention of OBPA and the USDA Agency of primary interest in the matter.

•http://www.sba.gov/ombudsman/dsp_boards.html -regions and information

D. Washington Contacts for SBREFA-related matters involving FSIS

[List of persons to contact should be transmitted to CSO's via memo.]

FSIS Contacts:

Dr. Barbara Masters, Assistant Deputy Administrator for Field Operations

Dr. Daniel L. Engeljohn, OPPD Assistant Deputy Administrator for Policy Analysis and Formulation

Mr. Ronald Hicks, Assistant Administrator for Program Evaluation, Enforcement, and Review (PEER)

a. Washington Office staff will handle contacts with other offices, including:

1. The Office of the Secretary of Agriculture:

Office of Budget and Program Analysis (OBPA)
OBPA Director for Information Resource Management and Regulation: USDA contact with the Office of the National Ombudsman, Small Business Administration

2. The Small Business Administration:

Office of National Ombudsman

Federal agency liaison

C. Non-retaliation policy.

All Agency personnel, and especially those in front-line enforcement positions, are not to retaliate in any way against establishment owners, operators, or employees who have filed comments with the Office of the National Ombudsman, Small Business Administration.

VIII. OFFICE OF POLICY AND PROGRAM DEVELOPMENT

A. OPPD Policy Analysis and Formulation units exercise SBREFA-related responsibilities in the following areas:

1. General SBREFA-related activities:

- a. Maintains liaison with the Department's Office of Budget and Program Analysis (OBPA) on matters relating to SBREFA.
- b. Arranges with OFO for FSIS representation at hearings of the Regional Small Business Regulatory Enforcement Fairness Boards.
- c. Coordinates the preparation and submission through OBPA and to SBA of the FSIS relating to USDA's contribution to the National Ombudsman's annual Report to Congress.
- d. Responds to inquiries from ONO/SBA on FSIS activities that may have SBREFA compliance implications.
- e. Responds to inquiries from ONO/SBA following comments by small businesses on FSIS activities.
- f. Compiles information and prepares reports and other documentation for use by Department officials or Agency officials at meetings between USDA and other Executive Departments and Agencies, and with State and local officials and the private sector, on SBREFA-related matters.
- g. Through OFO and other program organizations, provides to CSO's materials for use in their in-plant activities or in meetings on SBREFA-related matters.

2. Rulemakings and Agency issuances:

- a. Analyzes each proposed and final regulation and other policy documents to determine what effects each is likely to have on small entities.
- b. Ensures that the Congressional Review Act provisions of SBREFA are met. OPPD ensures that copies of each final rule that FSIS publishes are provided to the President of the Senate and the Speaker of the House of Representatives.
- c. Prepares such FSIS issuances as may be necessary to ensure that the Agency is complying with the requirements of SBREFA including the APA and RFA amendments.

B. OPPD Program Development staffs carry out SBREFA-related responsibilities in the following area(s):

1. Compliance Guidance:

- a. OPPD staffs coordinate with other staffs the preparation of small business compliance guides for regulations that are likely to have a significant impact on a substantial number of small entities.
- b. OPPD staffs solicit the contributions of FSIS technical staffs to contribute their expertise in the development of small business compliance guides.

2. Small and Very Small Establishment Outreach:

The Office of the Small and Very Small Plant Coordinator arranges technical assistance to small and very small plants to help them understand HACCP. This Office also provides access to coordinators, materials, material development and distribution, etc. [\[Add more.\]](#)

IX. EVALUATION OF FSIS SBREFA EFFORTS

A. Program Oversight

B. Formal Evaluation

Role of Office of Management